

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in October 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-349

Trade Name: Draxxin® 25 Injectable Solution
Ingredients: Tulathromycin
Sponsor: Zoetis Inc.
Approval Date: July 9, 2013
Status: Rx
Route: Intramuscular injection
Species: Swine
Drug Form: Injectable Solution
Concentration: 25 mg/mL
Indications: For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.
Exclusivity: 3 years
Patent:

Patent Number	Expiration date:
6,777,393	May 29, 2018
6,936,592	May 29, 2018
6,420,536	May 24, 2019
6,329,345	November 18, 2019
6,861,412	November 28, 2020
6,514,945	January 24, 2021

21 CFR 522.2630

78 FR 63870-63872

NADA Number: 141-360

Trade Name: EQUISUL-SDT®
Ingredients: Sulfadiazine/Trimethoprim
Sponsor: Aurora Pharmaceutical, LLC
Approval Date: July 26, 2013
Status: Rx
Route: Oral
Species: Horses
Drug Form: Oral Suspension
Concentration: 400 mg/mL combined active ingredients (333 mg/mL sulfadiazine and 67 mg/mL trimethoprim)
Indications: For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus*.
Exclusivity: 3 years
Patent:

Patent Number	Expiration date:
6,211,185	May 5, 2019
6,410,543	May 5, 2019
6,800,631	May 5, 2019

21 CFR 520.2612

78 FR 63870-63872

ANADA Number: 200-542

Trade Name: Engain™ 9 and Engain™ 45
Pioneer: Paylean® 9 and Paylean® 45
Ingredients: Ractopamine hydrochloride

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Sponsor: Zoetis Inc.
Approval Date: July 16, 2013
Status: OTC
Route: Oral, in feed
Species: Finishing swine
Drug Form: Type A medicated articles
Concentration: 9 g/lb and 45.4 g/lb
Indications: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.

21 CFR 558.500

78 FR 63870-63872

ANADA Number: 200-548

Trade Name: Actogain™ 45
Pioneer: Optaflexx™ 45
Ingredients: Ractopamine hydrochloride
Sponsor: Zoetis Inc.
Approval Date: July 18, 2013
Status: OTC
Route: Oral, in feed
Species: Cattle fed in confinement for slaughter
Drug Form: Type A medicated articles
Concentration: 45.4 g/lb
Indications: **Complete Feed:**
(8.2 – 24.6 g/ton) - For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.
(9.8 – 24.6 g/ton) - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.
Top Dress Feed:
(70-400 mg/head/day) – For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

21 CFR 558.500

78 FR 63870-63872

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 139-237

Trade Name: Factrel® Injection
Ingredients: Gonadorelin injection
Sponsor: Zoetis Inc.
Approval Date: June 28, 2013

This supplement provides for addition of a new indication for use with Lutalyse® (dinoprost tromethamine) Sterile Solution to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.

21 CFR 522.1077

78 FR 63870-63872

Sponsor Change

ANADA Number: 200-348

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The following corrections or additions to the list were published in the Federal Register in October 2013.

Previous: ECO LLC

New Sponsor: SmartVet USA, Inc.

Drug Labeler Code: 086001

21 CFR 524.1193 *78 FR 63870-63872*